OVATION
Pharmaceuticals, Inc.

June 15, 2005

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear Sir or Madam:

Re: Draft Guidance – *FDA's "Drug Watch" for Emerging Drug Safety Information*

Below you will find our comments regarding the above-referenced guidance document.

1. Posting unsubstantiated safety concerns regarding a drug to the "Drug Watch" list could be potentially deleterious for the uneducated population. A patient who does not understand the science or significance of the posted risk could decide to stop taking a prescribed medication for a condition that requires treatment. To provide the information that would satisfy the Agency and hence remove the product from the list could take years. This could be extremely dangerous to patients in the interim.

2. If factual information about newly observed safety issues associated with known risks, or risks associated with off-label uses of a drug is posted, the guidance document will need to define which risks will be posted as emerging safety issues. Quite possibly, all emerging safety issues could be posted. Is this the Agency's intent for this website? Maintenance of the website must be defined in the guidance document with specific timeframes. Is the Agency willing to commit to a schedule for updating the proposed website?

3. The guidance document must adequately explain why it is necessary to post information about emerging safety risks which the Agency believes may be associated with a drug, but that could possibly be avoided with the appropriate patient selection, monitoring and use of concomitant therapy. In the draft guidance document, the Agency proposes to direct these statements to "prescribers." These prescribers could be better directed to the currently active **Drugs@FDA** website link, which then links to product package inserts.

4. When information is posted to the proposed website, how soon in advance will drug sponsors be notified? What, if any, collaborative sponsor proposals will be considered by the Agency? Would the Agency consider posting the

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drug sponsor's response to the posted risk? Would the Agency consider adding a link to the risk for sponsor's email so that patients can request additional information if desired?

5. The Agency must revise the guidance document to replace ambiguous terms such as "regularly" and "promptly" with definitive timelines.

6. According to the April 25, 2005 **Pink Sheet**, in an April 15, 2005 meeting of FDA's Science Board, FDA announced plans for this drug safety website as well as a Drug Safety Oversight Board. The **Pink Sheet** stated that the Board will establish criteria for including drugs on the website. The first criterion is "whether the drug's adverse effect is 'something real,' rather than a 'specious finding' that may have an alternative explanation." The decision tree for this evaluation must be made available in the guidance document.

   The second criterion is whether "patients and practitioners are going to use this information for risk/benefit analysis in using a product." The guidance document must define the evaluation process for making this decision.

Thank you for the opportunity to express our concerns.

Sincerely,

Kathryn B Patterson

Kathryn B. Patterson
Associate Director, Global Regulatory Affairs